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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/489,088	01/21/00	KWON S	7010-0014

HM12/0808

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EXAMINER	
GHALI, I	
ART UNIT	**PAPER NUMBER**
1615	4

DATE MAILED: 08/08/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/489,088	Kown et al.
Examiner	**Group Art Unit**
Isis Ghali	1615

☒ Responsive to communication(s) filed on *Jan 21, 2000*

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) *1-40* is/are pending in the applicat

Of the above, claim(s) _____ is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1-40* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

The receipt is acknowledged of applicants declaration and fee, filed 6/12/2000.

Specification

1. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Double Patenting

2. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

3. Claims 1-40 provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-40 of copending Application No. 09/235,944. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1-32 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claim 1 is reciting "a first transdermal drug delivery device" which means there is a second transdermal drug delivery system, however, no second drug delivery system is recited in the claim. The claims are non enabling unless the limitation of claim 14 is included in the independent claim 1.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various

claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 1-4, 11, 12, 17, 19, 20-23 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bellhouse et al., US 5,630,796 ('796).

US '796 is teaching a needleless syringe for effective transdermal delivery of particles containing a therapeutic agent such as viruses or proteins (antigen), insulin with a carrier (adjuvant) or a placebo. Injection velocities may be between 200 up to 3000 m/sec. and the particle size ranges from 0.1 to 250 micrometer. The particles can be made from metal. The drug particles can be encapsulated. More than one therapeutic agent can be injected together. See the abstract, col.2, lines 30-37; col.4, lines 1-23, 40-55; col.8, lines 17-20; col.10, example 2.

The reference does not teach topically positioning a transdermal drug delivery device or a first occlusive dressing comprising a therapeutic agent.

However, it is obvious to one having ordinary skill in the art at the time the invention was made to dress the site of the injection with an occlusive dressing or a transdermal device after injection as a routine technique and including a therapeutic agent in the TTS is flowing from the transdermal delivery art or from the teaching of the reference that more than one therapeutic agents can be delivered together. One having ordinary skill in the art would have been delivered

particles coated with permeation enhancer motivated by the teaching of the reference that the particles are coated to control the permeability (col.4, lines 16-17), and means to enhance the penetration or control the release would have been used for coating with reasonable expectation of success of delivering the drug particles transdermally and without a needle.

8. Claims 1-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over '796 in view of Mak, US 5,962,477 ('477).

US '477 is teaching formulation for topical administration of therapeutic agents in the form of powder such as proteins, peptides, inorganic ions (metal placebo), oligosaccharides or an antigen. Delivery device can be active or passive in the form of transdermal patch, occlusive dressing, or transmucosal delivery device and absorption enhancer can be used. The occlusive dressing optionally applied to the skin after the therapeutic agent is applied to area of the skin to be treated. The reference also teach the pretreatment of area of skin up on which the drug is to placed prior to attachment of the transdermal patch to the skin. The reference teaches the use of two separate dosage forms at the same time. See col.5, lines 1-8; col.7, lines 17-25; col.42, lines 62-65; col.43, lines 10-18, 33-34; col.46, lines 55-56; col.48, lines 18-20, 54-56; col.52, lines 25-26, 38-44; col.53, lines 2-11, 37-46; col.55, lines 23-33; col.59, lines 5-19.

Accordingly, it would have been obvious to one having ordinary skill in the art at the time the invention was made to apply the drug to the skin by the needleless syringe of '796 after pretreatment of the skin with a transdermal device as taught by '477 and then apply a another

transdermal device containing the same or different drug, with reasonable expectation of the achieved method to administer antigen, adjuvant and placebo through the skin.

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 6,030,374 disclosing an ultrasound enhancement of percutaneous drug absorption.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Isis Ghali whose telephone number is (703) 305-4048. The examiner can normally be reached on Monday-Friday from 8:30 to 5:30 Eastern time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Isis Ghali

Patent Examiner

July 31, 2000.

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600